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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,842	01/11/2002	Issam Raad	UTSC:669US	7921

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,842	RAAD ET AL.	
	Examiner	Art Unit	
	ELIZABETH L. MCKANE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008 and 03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69,91-98,100 and 117-126* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69,91-98,100 and 117-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09042008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 3 November 2008 is acknowledged. Claim 100 has been included in the elected group.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 69, 91-96, 114-119, 121, 122, and 124-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luthra et al. (WO 00/65915) in view of Pelerin (US 2002/0009693).

Luthra et al. teaches a method of disinfecting a medical device by applying a composition containing chlorhexidine thereto. See col.1, lines 16-23; page 4, line 26; page 5, lines 21-23. The medical device may be fabricated from a polymeric material such as silicone (page 1, lines 25-27). Luthra et al. fails to disclose including a dye in the composition.

However, Pelerin discloses the use of gentian violet in a chlorhexidine-containing disinfecting composition to indicate to the user where the composition has been applied. See paragraph [0012]. The chlorhexidine is used in an amount of up to 10%, preferably 0.5-5%. The gentian violet is used in an amount of up to 5%, preferably 0.5-2%. These concentrations fall within the claimed ratios. It would have been obvious to one of

ordinary skill in the art at the time of the invention to add gentian violet to the composition of Luthra et al. in order to provide a means of indicating wherein the composition has been applied to the medical device, thereby assuring the practitioner that the device has been completely treated. Moreover, one would have found it obvious to maintain the relative concentrations disclosed by Pelerin as being successful in a disinfecting composition.

As the medical devices of Luthra et al. include *inter alia* catheters, blood bags, and dialysis membranes - it is deemed obvious to apply the disinfecting function disclosed by Luthra et al. to disinfect other fluid pathogen sources, such as various catheters and endotracheal tubes.

While Luthra et al. primarily discloses use of the composition to coat polymeric medical devices, Luthra et al. generally teaches that the "term medical device as used herein is intended to encompass the full range of devices for intimate contact with the human or other mammalian body, or with the corresponding body fluids". Given this teaching, one of ordinary skill in the art would have found it obvious to apply the method of Luthra et al. to silk sutures as being an article in intimate contact with the human body and corresponding body fluids.

4. Claims 97, 120, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luthra et al. and Pelerin as applied to claims 69, 118, and 122 above, and further in view of Ibsen et al. (US 4,204,978).

The combination *supra* discloses gentian violet as the dye. The use of brilliant green is not disclosed. Ibsen et al. discloses the equivalence of brilliant green

(malachite green) and gentian violet as dye indicators. Thus, it would have been obvious to one of ordinary skill in the art to substitute the brilliant green of Ibsen et al. for the gentian violet of Luthra et al. with Pelerin as the results of doing so would have been expected.

5. Claims 98 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelerin in view of Ibsen et al..

Pelerin discloses the use of gentian violet in a chlorhexidine-containing disinfecting composition to indicate to the user where the composition has been applied. See paragraph [0012]. The chlorhexidine is used in an amount of up to 10%, preferably 0.5-5%. The gentian violet is used in an amount of up to 5%, preferably 0.5-2%. These concentrations fall within the claimed ratios. Pelerin further teaches that the composition is "typically dabbed or dropped" onto the specific site. The dental art typically uses swabs and/or gauze for dabbing and a dropper (medical device) for dropping. The contact of the composition of Pelerin with these articles during use of the composition to disinfect other surfaces would intrinsically meet the claim limitation of disinfecting a medical device. Pelerin does not disclose the use of brilliant green as the dye. Ibsen et al. discloses the equivalence of brilliant green (malachite green) and gentian violet as dye indicators in dental compositions. Thus, it would have been obvious to one of ordinary skill in the art to substitute the brilliant green of Ibsen et al. for the gentian violet of Pelerin as the results would have been expected.

Response to Arguments

6. Applicant's arguments filed 11 June 2008 have been fully considered but they are not persuasive.

7. With respect to the combination of Luthra with Pelerin, Applicant argues on page 14 of the Response that Luthra does not teach applying any chlorhexidine containing composition to a medical device. In fact, Applicant asserts that Luthra is concerned only with devices composed of polymers wherein the polymer contains a biguanide moiety. While the Examiner agrees that this is *one* of the embodiments disclosed by Luthra, it is by no means the only or even the preferred embodiment disclosed by Luthra. To this point, Applicant's attention is directed to the Abstract wherein it is stated that 'solutions and emulsions …can be used for coating…articles." Further, on page 6, line 26 to col.7, line 9, Luthra discloses that a polymeric medical device can be 'coated with the polymeric material incorporating the infection resistant biguanide compound,' and on page 8, lines 2-3, it is taught that the composition 'may be applied to articles by sprays, to form thin surface films.' Luthra specifically teaches that the articles may be medical devices. Further, on page 4, line 26 'chlorhexidine' is disclosed as a preferred biguanide. Thus, it is evident that Luthra does indeed teach applying a composition containing chlorhexidine to the surface of a medical device.

8. On pages 15-21 of the Response, Applicant submits alleged evidence of unexpected results. Nevertheless, it is well settled that a patent cannot be granted for an applicant's discovery of a result, even though it may be unexpectedly good, which

would flow logically from the teaching of the prior art. In re Rau, 117 USPQ 215 (CCPA 1958).

9. On page 22 of the Response, Applicant argues that neither of Pelerin or Ibsen teach a method for disinfecting any of the items set forth in claim 98. However, the method of disinfecting such a surface is intrinsic in the method of Pelerin. In the method of Pelerin, a medical device (swab, gauze, dropper) is contacted with the disinfecting composition during use thereof, thereby disinfecting the medical device.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is

(571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
20 January 2009